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REMARKS

Specification

The abstract has been amended to conform more closely to the claimed invention. No new matter is added. The amendments to the Specification which were recommended in the Office Action were otherwise implemented. Applicants thank the Examiner for the suggestions.

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Claims

Claim Rejections Under 35 USC §103

Claims 1-2, 4, 6-7, 8-11, 16, 21-24, 26-27, 28-37, 43-46, 48-49, and 50-59 were rejected as obvious. These claims are canceled by this amendment rendering their rejection moot. However, their patentability over the cited art and arguments is discussed below.

Claim 3 stands rejected as obvious over Polaschegg in view of O'Keeffe, T.G. et al. and Johnson, D.A. et al. in view of Sauges, A. et al. Claim 3 is amended to place it in independent form and to emphasize the difference between what is claimed and the cited art as discussed further below. The Office Action states that Polaschegg teaches an extracorporeal blood circuit with a blood leakage detecting apparatus. The cited leakage detecting detector in Polaschegg Fig. 1, reference numeral 128 is an opacity or color sensitive detector that detects the leakage of blood into otherwise clear dialysate. This type of detector differs markedly from the type used in the present invention. The Office Action states that certain elements not shown by Polaschegg are obvious to add. These include (paraphrasing) a funnel mechanism, a safety response upon detection of a blood leak, and disposing different sensors in

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different parts of a circuit because of the different modes of leakage in the different parts.

Claim 3 has been amended to recite: "detecting liquid outside a normally dry environment of a first portion of a blood circuit." This recitation is markedly different from what is shown by Polaschegg. Also, the Office Action states that Polaschegg teaches positive and negative pressure portions of a blood circuit, however, none of the references shows or teaches "detecting air inside a second portion of a blood circuit located remote from said first portion such that fluid is not detectable from said second portion ... [and] applying a positive gauge pressure to said circuit during a first time and applying a negative pressure to said blood circuit during a second time." None of the obviousness arguments in the Office Action addresses these differences and Applicants therefore propose that claim 3 is thus allowable over the prior art of record.

The remaining rejected claims have been canceled.

Claims 5, 12-15, 25, 38, 42, and 60-64 were found to be allowable over prior art if amended to render them independent of rejected base claims. These claims have been so and as suggested in the Office Action to make them clearer. These claims should therefore be allowable.

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New Claims

Claim 65 recites

detecting blood or liquid outside a normally dry first portion of a blood circuit; detecting air inside a second portion of the blood circuit that is remote from the first portion; said step of detecting air including periodically reversing a flow in said blood circuit; and generating an alarm signal signifying the occurrence of either or both types of fluid leakage detections in said steps of detecting

Claim 65 is essentially a recitation of the Examiner's statement of reasons for allowance. None of the references teaches to detect liquid outside the circuit, detect air or bubbles inside the circuit while periodically circuit reversing flow. Also, the detecting happens at least at respective portions. The Office Action does not argue against the patentability of above differences and the claimed combination should therefore be allowable. Claim 66 is similar by recites "periodically generating a negative pressure." The above arguments for patentability apply equally to claim 66. Claims 67 and 68 depend from claim 66 and should therefore also be allowable for the same reasons.

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Claim 69 is also a recitation, essentially, of the Examiner's statement of reasons for allowance and should therefore be allowable.

Claim 70 recites,

a liquid detector ... to detect blood or liquid outside a first portion of a blood circuit; an air detector ... to detect air inside a second portion of the blood circuit that is remote from the first portion; a ... mechanism ... to periodically generate a negative pressure ... such that air is ... infiltrated in portions that are otherwise not under negative pressure; and an alarm configured to signify the occurrence of a leak in response [thereto]

None of the references teaches the above combination of leak detection by detecting liquid and air by respective means in respective portions of a blood circuit while periodically generating a negative pressure. The allowability of the above claim is believed to be consistent with the Examiner's analysis reflected in the Office Action. Claim 71-73 depend from claim 70 and should therefore also be allowable.

Claim 74 recites,

during a treatment operation, detecting liquid outside a blood circuit, at least a first portion of which is under non-negative pressure during a

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treatment operation; creating a temporary negative pressure at least two times during said treatment operation in at least a second portion of said blood circuit effective to cause air to infiltrate said second portion; detecting said air caused to infiltrate by said step of creating;

None of the references teaches the above combination of leak detection by detecting liquid and air by respective means in respective portions of a blood circuit while temporarily creating a negative pressure. Also, the allowability of the above claim is believed to be consistent with the Examiner's analysis reflected in the Office Action since no reasons for rejection are given in the Office Action.

Claim 75 recites,

during a treatment operation, detecting liquid outside of a first portion of a blood circuit that is under non-negative pressure, the outside being normally dry; detecting air inside a second portion of a blood circuit by reversing blood flow at least two times during said treatment operation in said second portion effective to cause air to infiltrate said second portion;

None of the references teaches the above combination of leak detection by detecting liquid in a normally dry outside of a

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blood circuit and detecting air by respective means in respective portions of a blood circuit while reversing a flow of blood. Also, the allowability of the above claim is believed to be consistent with the Examiner's analysis reflected in the Office Action and also because no reasons for rejection are given in the Office Action.

Claim 76 recites,

during a treatment operation, detecting liquid outside a first portion of a blood circuit that is under non-negative pressure; detecting air inside a second portion of a blood circuit by creating a temporary negative pressure at least two times during said treatment operation in said second portion effective to cause air to infiltrate said second portion;

None of the references teaches the above combination of leak detection by detecting liquid in a normally dry outside of a blood circuit and detecting air by respective means in respective portions of a blood circuit while reversing a flow of blood at least two times during treatment. Also, the allowability of the above claim is believed to be consistent with the Examiner's analysis reflected in the Office Action and also because no reasons for rejection are given in the Office Action. Claim 76 is similar to claim 75 except that it recites

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creating a negative pressure rather than reversing a flow of blood.

The other new claims 77 through 83 contain similar limitations to the above claims. The claims are believed to be allowable consistent with the Examiner's analysis reflected in the Office Action and also because no reasons for rejection are given in the Office Action.

If the Examiner requires clarification of any issues raised in this response, the Examiner is invited to call the undersigned at (202) 778-1118.

Respectfully submitted,

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